



# **CORE COMPETENCIES**

Focusing on our clients' most pressing business and compliance needs, Nopras is an end-to-end service provider in three core competencies:



#### ► LIFE SCIENCES TECHNICAL SERVICES.

Nopras Technologies project teams will manage the day-to-day operations of all or part of project portfolio to help improve the reliability of mission critical systems and control maintenance or waste. Our project partnerships are based on executing to agreed upon levels of service. Our Optimized Delivery Model allows clients to drive labor costs down and refocus internal resources on core functions.

### PROCESS / ORGANIZATIONAL EXCELLENCE.

Nopras Technologies teams will develop customized regulatory compliance solutions, convert existing solutions and integrate front-end and back-end systems to accelerate the return on our clients' investments.

Combining our own proprietary tools and methods with those recognized by the industry, we deliver projects on time and in the most cost-effective way possible to meet or exceed business and compliance goals, regardless of a project's scope or schedule.

Clients' can take advantage of Nopras' capability to ensure highest quality, safety and efficiency standards are maintained throughout our portion of the project including new product development and launch or re-design for manufacturing using our proven risked-based approach that reduces costs without compromising compliance with laws and international regulations.



### PRECLINICAL AND CLINICAL STUDY DESIGN

Nopras Technologies Strategic Product Development (SPD) group will assist you to minimize the time to achieve key milestones and maximize the value of your products under development. The SPD team will work closely with your clinical development team to strategically integrate the therapeutic and functional expertise necessary for success in today's complex commercialization environment.

**Nopras Technologies** experts are available to our clients in the early planning stages to provide:

- Detailed and comprehensive development strategies for individual compounds.
- Guidance and strategy on lifecycle management for new and existing therapies.
- Clinical development plans and individual protocols
- Medical and scientific support to regulatory submission planning and preparation
- Input on site selection strategies
- Support of relationship building with Key Opinion Leaders
- Enrollment enhancement solutions.

### **VALUE ADDED STAFFING**

Nopras Technologies will deliver the team with the precise skills and experience at the right time to help clients design and implement compliance solutions and reduce the need to increase permanent staff.

Our incumbent staff of senior level professionals from industry leaders average over 20 years of experience in product life cycle; from design, laboratory analysis, clinical development, through manufacturing and product tracking. Our clients can quickly expand bandwidth, acquire expertise in new technologies and augment their staff without compromising compliance with laws and international regulations or deadlines.

# OPTIMIZED DELIVERY MODEL

One of the most innovative ways Nopras saves clients money and stays attentive to their unique business needs is through flexible delivery and resource management.

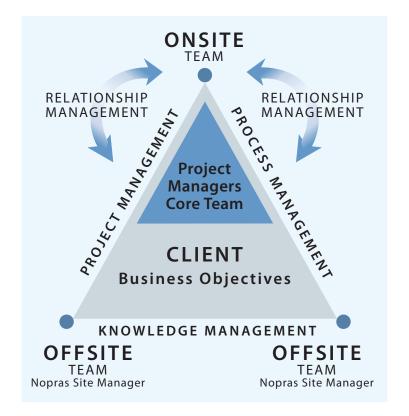
Nopras helps clients consider their options:

- What is the ideal balance between onsite and offsite staff for any particular situation?
- How can I ensure that a high level of quality, productivity and communication will be maintained, regardless of location?
- What cost savings will I receive from flexible delivery and resource model?

**Nopras' Optimized Delivery Model** provides clients with blended onsite and offsite teams – customized to meet each project requirements. The Optimized Delivery Model is flexibly designed to drive labor costs down while maintaining our founding principle of providing our customers with only the highest levels of customer service.

The foundation of the Optimized Delivery Model is Nopras' strong commitment to quality DELIVERY MANAGEMENT – the integration of world-class project management, methods and tools. Regardless of location, Nopras ensures consistency of process via global access to our Knowledge Management System.

Across all core competencies, Nopras' focus on clients, on strong pharmaceutical, biotechnology/biologics and medical device processes and on flexible resource management creates true optimal delivery and delivers business value quickly. *This is Nopras' value proposition to our clients*.



# **CORPORATE PROFILE**

Nopras Technologies is a FDA regulatory consulting company focused on helping pharmaceutical, biotechnology/biologics and medical device organizations deliver business value.

- ► Nopras Technologies core competencies in Life Sciences Technical Services, Process/Organizational Excellence and Preclinical and Clinical Study Design – all customized to meet clients business needs.
- Central to Nopras value proposition is our firm's unique Optimized Delivery Model (ODM) which combines strong delivery management processes with flexibility:

#### **Focus On Clients**

Not given to reinventing itself, Nopras remains focused on the FDA Regulatory Compliance business which is most important to our clients. We invite you to consider some of the questions we pose to our clients:

- What are you doing to reduce the operating costs in your organization?
- What steps are you taking to accelerate returns from your regulatory compliance initiatives?
- What alternative regulatory compliance strategies do you have in place to attack the project backlog without adding permanent employees to the payroll?

Focus On Quality & Long-Term Client Partnerships Nopras' Optimized Delivery Model combines the clear communications of onsite service, and high productivity gains of offsite development and lower labor costs.



### NOPRAS' MISSION



Nopras' mission is to assist our clients confront and overcome the business and compliance challenges associated with regulatory, quality and project management issues by providing an exacting match of resource and need to deliver results to meet expectations on time and within budget.

Nopras Technologies ensures Quality Excellence through a comprehensive and effective Quality System with an ongoing focus and commitment to the following objectives:

- Maintaining a reputation of absolute trust built on a history of reliability, dedication, ethics and integrity.
- Achieving high quality standards through compliance with requirements and maintenance of the effectiveness of the Quality Management System.
- Providing total customer satisfaction to medical providers from design to end use.
- Nopras' Quality Management System is in accordance with world regulatory bodies requirements. We emphasize a total quality assurance approach to all aspects of our consulting business. Awareness of Quality Systems and procedures is maintained through employee training and is practiced company-wide.

The Nopras Quality Management System provides the organizational structure to ensure that products are processed, manufactured, controlled, and distributed according to the appropriate regulatory requirements and corporate policies/procedures.

Continuous quality improvement is the basis for our Quality Management System. The periodic reviews of our system identify the strategic plans required to develop, implement, and modify the Quality Management System and identify the processes, controls, resources, and skills necessary to meet ongoing quality requirements.

Our goal is to continue to help our clients make better decisions faster, which has become even more important in these changing technological times.

We pride ourselves on our high levels of client retention and unlike many other companies in this industry; we invest more in our current clients than in pitching for prospective clients. This is not only reflected in the service we provide but in a number of added value services.

We are continually striving to improve our service offerings in line with this mission, and this endeavor is no different. We are listening, so please continue to share your thoughts with us and we will continue to improve our services to help better meet your goals.



Nopras Technologies headquartered in Novi, Michigan, just outside of Ann Arbor, Michigan, the home to the University of Michigan, one of the premier research institutions in the world.



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